# IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ALABAMA SOUTHERN DIVISION

ROBERT BURGETT, JR.,	)
Plaintiff,	) CIVIL ACTION:
<b>v.</b>	) DEMAND FOR JURY TRIAL
ASTRAZENECA PHARMACEUTICALS LP,	)
ASTRAZENECA LP, and ZENECA, INC	)
	)
Defendants.	)

#### **COMPLAINT FOR DAMAGES**

Plaintiff ROBERT BURGETT, JR. ("Plaintiff"), makes the following allegations against defendants ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA LP, and ZENECA, INC.

### NATURE OF THE ACTION

- 1. This Complaint arises out of significant personal injuries that Plaintiff sustained as the proximate result of his use of the pharmaceutical product Seroquel, which defendants designed, manufactured, promoted, and distributed into the stream of commerce in Alabama, Tennessee and across the United States. Defendants represented that the Product was safe and effective. In fact, the Product was not safe and effective; instead, it was grossly defective and inappropriate for its intended purpose in that, *inter alia*, it caused, contributed to, and/or worsened Diabetes or a Diabetic condition.
- 2. As is outlined with specificity in this Complaint, *infra*, the Manufacturer Defendants knew that the Product was defective, knew that the Product was not safe and

effective, and knew that the use of the Product by consumers such as Plaintiff created an unacceptable and unreasonable risk of serious and debilitating injuries and illnesses, including the development or progression of Diabetes or a Diabetic condition

3. The Manufacturer Defendants further knew that the risks associated with the Product were grossly disproportionate to those of other similar products on the market but, despite their knowledge, the Manufacturer Defendants did nothing to eliminate - or mitigate those risks.

#### **PARTIES**

- 4. Plaintiff Robert Burgett, Jr. is a resident of the State of Alabama.
- 5. Defendant AstraZeneca Pharmaceuticals LP is a Delaware limited partnership, and all times mentioned herein was doing business in the States of Delaware and Virginia, and all other of the United States. Defendant AstraZeneca LP is a Delaware limited partnership, and all times mentioned herein was doing business in the States of Delaware and Virginia. Defendant Zeneca, Inc., is a Delaware corporation, and is doing business in the State of Delaware and Virginia. Said defendants are hereinafter referred to as "AstraZeneca" or "Defendants".
- 6. In approximately November 0f 2004, Plaintiff Robert Burgett, Jr. was prescribed and began taking the prescription drug Seroquel® (quetiapine).
- 7. Subsequently, as a result of the ingestion of Seroquel, Plaintiff developed diabetes mellitus in approximately February of 2007 and was injured.
- 8. Plaintiff has filed this lawsuit within any applicable statute of limitations period. Plaintiff acted with diligence in attempting to discover any injury caused by the ingestion of the atypical anti-psychotic, Seroquel<sup>®</sup>, including but not limited to following the advice of plaintiff's

physician. Plaintiff's injury was inherently unknowable and Plaintiff was blamelessly ignorant of the fact that Seroquel can cause diabetes, pancreatitis, and other hyperglycemia-related adverse events until some time after the product label for Seroquel was changed to add a warning regarding diabetes and hyperglycemia and also the need to monitor patients for those conditions, until Plaintiff had completed appropriate testing, which would have either shown the presence of diabetes mellitus, pancreatitis or other injuries, which was then diagnosed by plaintiff's physician. Plaintiff could not have brought a cause of action against Defendants until Plaintiff discovered that any injury detected was a result of the action and/or omissions of Defendants. Plaintiff was prevented from discovering, did not discover and/or could not have discovered Plaintiff's injuries earlier because of the Defendants' fraudulent misrepresentations, concealment of the facts and/or the nature of the injuries involved, as more specifically alleged herein.

### JURISDICTION AND VENUE

- 9. Defendants are Delaware Corporations. Defendants are directly involved in the distribution of their products throughout the United States, including Florida. Jurisdiction is proper for diversity of jurisdiction and the amount in controversy exceeds the sum specified in 28 U.S.C. §1332.
- 10. Defendants are incorporated and have their principal places of business in states other than the state where Plaintiff's decedent resided. Venue in this Court is proper in this District because Defendants transact business in this District.

### FACTUAL BACKGROUND

- 11. In June 1997, the Food and Drug Administration ("FDA") approved the newest "atypical anti-psychotic", Seroquel (quetiapine fumarate), for use in the United States. At that time, Seroquel was approved for use in dosages of 50mg, 100mg, or 200 mg.
- 12. The prescription drug "Seroquel" (quetiapine fumarate) is an "anti-psychotic" medication, belonging to a class of drugs referred to as "atypical anti-psychotics." (Other atypicals include Zyprexa (Eli Lilly), Risperdal (Johnson & Johnson), and Abilify (Bristol-Myers Squibb), which have been in use in the United States since the early to mid 1990's.
- 13. Seroquel is a medication commonly prescribed to patients to aid in the treatment of mental disorders including schizophrenia. The pharmacologic action of Seroquel is thought to be dependent on its ability to block or moderate the level of dopamine; a chemical found in the brain that in excessive amounts is believed to cause abnormal thinking and hallucinations. It appears to work primarily by blocking neurotransmitter sites of serotonin and dopamine, as well as muscarinic and alpha-adrenergic, and histamine receptors.
- 14. AstraZeneca obtained, licensed, manufactured, promoted, marketed, developed and placed in the stream of commerce the pharmaceutical "quetiapine fumarate" which was sold in the United States under the trade name "Seroquel."
- 15. From at least 1997 through today, the Defendant manufactured, labeled, packaged, distributed, supplied, marketed, advertised, dispensed and sold, and by said activities, caused Seroquel to be placed into the stream of commerce throughout the United States, including the State of Illinois, and to ultimately reach the s for consumption.
- 16. At all times material hereto, AstraZeneca did manufacture, create, design, test, label, sterilize, package, distribute, supply, market, sell, advertise, warn, and/or otherwise caused

the product Seroquel to be placed into the stream of commerce, and ultimately to be ingested by the Plaintiff.

- 17. Seroquel was widely advertised, marketed and represented by AstraZeneca as a safe and effective atypical anti-psychotic.
- 18. The product warnings for Seroquel in effect during the relevant time period were vague, incomplete or otherwise wholly inadequate, both substantively and graphically, to alert prescribing physicians as well as consumer patients of the actual risks associated with this drug.
- 19. The use of Seroquel has been has been known to cause serious and sometimes fatal injuries to the liver, kidneys, and pancreas. Its adverse effects include, but are not limited to, ketoacidosis, pancreatitis, and diabetes mellitus, and other serious health problems associated with diabetes including heart disease, blindness, coma, seizures, and death. In addition to an increased risk of developing diabetes mellitus, and the serious complications streaming therefrom, including seizures, coma, death, liver disease, kidney disease, blindness, other serious side effects including rapid weight gain, pancreatitis, increased thirst, urinary frequency and hyperglycemia have been attributed to Seroquel.
- 20. The reported risk associated with Seroquel and the onset of diabetes is nearly 3.34 times higher than older drugs used to treat schizophrenia, such as Haldol. According to these reports, compared to other drugs in its class, Zyprexa, (Eli Lilly & Co.) 1.27 times more likely, and Risperdal (Johnson & Johnson) 1.49 times more likely, Seroquel has a much greater increased association with the onset of diabetes mellitus than any other anti-psychotic on the market.

- 21. Seroquel was marketed heavily by AstraZeneca as a safe and effective treatment for the treatment of schizophrenia, promising fewer side effects than other similar treatments including the other atypical antipsychotics on the market.
- 22. AstraZeneca, through its marketing department, its sales managers, and field sales force promoted the drug for uses beyond its approved indications, offering incentives to doctors to increase prescriptions. Through these marketing efforts, AstraZeneca was able to capture a larger market share in the anti-psychotic market.
- 23. These marketing efforts were designed and implemented to create the impression in physicians' minds that Seroquel was safe and effective for his patients, and that it carried less risk of side effects and adverse reactions than other available treatments.
- 24. The marketing and promotion efforts of AstraZeneca, its advertisers, and sales force served to overstate the benefits of Seroquel, and minimize and downplay the risks associated with the drug. These promotional efforts were made, while fraudulently withholding important safety information from the physicians, the FDA, and the public, specifically that AstraZeneca was aware of numerous reports of diabetes associated with the use of Seroquel, well beyond the background rate, and well beyond the rate for other anti-psychotic agents.
- 25. On August 22, 2003, new reports were issued which confirmed previous studies describing a link between the class of atypical antipsychotics and diabetes. These new reports, described an increased incidence of diabetes in patients receiving Seroquel, than in patients receiving older anti-psychotics, or even other atypicals, including Zyprexa, Clozaril, and Risperdal.
- 26. Clozaril (clozapine) was the first atypical introduced in the early 1990's. Risperdol, (risperidone), was approved for use in the United States in 1994. In September 1996

the Food and Drug Administration (FDA) approved another new atypical antipsychotic, Zyprexa (olanzapine), for use in schizophrenia, and Seroquel (quetiapine) was approved in September 1997.

- 27. These look-alike, copycat drugs are nothing new in the pharmaceutical industry, as major manufacturers, who have poured so much money into marketing, and away from research are forced to introduce copycat drugs to the market rapidly, to avoid losing market share to its competitors. The copycat drugs are often accompanied by promises of better efficacy and less side effects, but typically, they are approved without the requirements of significant testing, riding the coat tails of drugs already on the market.
- 28. The Japanese label for Seroquel provides a detailed warning regarding the risks of diabetes associated with Seroquel, and specifically informs physicians regarding the necessity of medical monitoring of patients on Seroquel. At the time the Plaintiff ingested Seroquel, the Defendant had not adopted this safer; more accurate, label for the U.S. distribution of Seroquel.
- 29. The Japanese label warns specifically of the diabetes risk, prominently in the beginning of the package label stating:
  - a. Quetiapine is contraindicated for use in patients with diabetes or a history of diabetes;
  - b. Quetiapine should be used with caution in patients with risk factors for diabetes, including hyperglycemia, obesity or a family history of diabetes;
  - c. Patients receiving quetiapine should be carefully monitored for symptoms of hyperglycemia and the drug should be discontinued if such symptoms occur. The symptoms of severe hyperglycemia include weakness, excessive eating, excessive thirst, and excessive urination; and,

- d. Physicians should educate patients and their family members about the risk of serious hyperglycemia associated with the quetiapine and how to identify the symptoms of hyperglycemia.
- 30. In regulatory action overseas, the Ministry of Health, Labor, and Welfare in Japan has ordered a Dear Doctor warning for AstraZeneca's quetiapine (Seroquel) after the ministry received 13 reports of serious side effects, including one death, since the drug's launch in that country in February 2001. Case reports involved elevated levels of blood glucose, diabetic ketoacidosis, and coma.
- 31. Japanese researchers report that severe weight gain can be a serious side effect of combination therapy involving atypical antipsychotics and certain SSRIs. In particular, in a retrospective chart review, they identified the combination of risperidone and paroxetine as associated with severe weight gain—as much as 14 kg over four months in one patient—that also resulted in diabetic complications.
- 32. While warning of the association of Seroquel with diabetes, increased glucose tolerance, ketoacidosis, weight gain, and the need for medical monitoring in Japan, AstraZeneca has left the US public and physicians in the dark.

### COUNT I – NEGLIGENCE

- 33. The allegations previously set forth are realleged and reincorporated and incorporated by reference within this count.
- 34. Defendants obtained, licensed, manufactured, promoted, marketed, developed and placed in the stream of commerce the pharmaceutical "quetiapine fumarate" which was sold in the United States under the trade name "Seroquel."

- 35. The prescription drug "Seroquel" (quetiapine fumarate) is an "anti-psychotic" medication belonging to a class of drugs referred to as "atypical anti-psychotics." (Other atypicals include Clozaril (Novartis), Zyprexa (Eli Lilly), Risperdal (Johnson & Johnson), and Abilify (Bristol-Myers Squibb), which have been in use in the United States since the early to mid 1990's.
- 36. Seroquel causes serious and sometimes fatal injuries to the liver, kidneys, and pancreas. Its adverse effects include, but are not limited to, ketoacidosis, pancreatitis, and diabetes mellitus, and other serious health problems associated with the onset of diabetes including heart disease, blindness, neuropathy, coma, seizures, and death.
- 37. From at least 1997 through today, Defendants manufactured, created, designed, tested, labeled, sterilized, packaged, distributed, supplied, marketed, sold, and advertised Seroquel, and, by said activities, caused Seroquel to be placed into the stream of commerce throughout the United States, including the States of Delaware and Virginia, and ultimately to be ingested by the Plaintiff.
- 38. The product warnings for Seroquel in effect during the relevant time period were vague, incomplete or otherwise wholly inadequate, both substantively and graphically, to alert prescribing physicians, as well as consumer patients, of the actual risks associated with this drug.
- 39. Seroquel, also known as quetiapine fumarate, is a medication commonly prescribed to patients to aid in the treatment of schizophrenia and manic episodes associated with bipolar I disorder. The pharmacologic action of Seroquel is unknown but is thought to be dependent on its ability to block or moderate the level of dopamine and/or serotonin; chemicals found in the brain that in excessive amounts may possibly cause abnormal thinking and hallucinations.

- 40. The anti-psychotic drug market is enormous. Defendants viewed Seroquel as a blockbuster product with significant projected growth potential. In 2004, Seroquel reached over \$2 billion in annual sales.
- 41. The use of Seroquel has been associated with an increased risk of developing diabetes mellitus, hyperglycemia, rapid weight gain, ketoacidosis, seizures, coma, death, pancreatitis, liver disease, kidney disease, blindness, and other serious side effects including neuroleptic malignant syndrome, tardive dyskinesia, hyperlipidemia, and hypercholesterolemia.
- 42. The risk associated with Seroquel and the onset of diabetes is higher than for older, less expensive drugs used to treat schizophrenia and compared to other drugs in its class.
- 43. Seroquel was marketed initially by Defendants as safe and effective for the treatment of schizophrenia, and later for bipolar mania, promising greater effectiveness and fewer side effects than other available antipsychotics.
- 44. Defendants, through their marketing department, sales managers, and field sales force, promoted the drug for uses beyond its approved indications, offering incentives to doctors to increase prescriptions in order to capture a larger share of the anti-psychotic market.
- 45. These marketing efforts were designed and implemented to create the impression in physicians' minds that Seroquel was safe and effective for their patients, and that it carried less risk of side effects and adverse reactions than other available treatments.
- 46. The marketing and promotion efforts of Defendants, through its advertisers and sales force, overstated the benefits of Seroquel and minimized and downplayed the risks associated with the drug. These promotional efforts were made, while fraudulently, willfully and wantonly withholding important safety information from the physicians, the FDA, and the public, specifically that Defendants were aware of numerous reports of diabetes associated with

the use of Seroquel, well beyond the background rate and well beyond the rate for other antipsychotic agents.

- 47. In 2002 the Japanese Ministry of Health & Welfare Ministry issued emergency safety information regarding the risk of diabetes, diabetic ketoacidosis, and hyperosmolar coma for patients prescribed Seroquel. On information and belief, prior to that time, Defendant AstraZeneca was involved in discussions with the Japanese agency regarding labeling changes for Seroquel atypicals.
- 48. Upon information and belief, the Japanese label warned specifically of the diabetes risk, prominently in the beginning of the package label stating:
- 49. Quetiapine fumarate is contraindicated for use in patients with diabetes or a history of diabetes.
- 50. Quetiapine fumarate should be used with caution in patients with risk factors for diabetes, including hyperglycemia, obesity or a family history of diabetes.
- 51. Patients receiving quetiapine fumarate should be carefully monitored for symptoms of hyperglycemia, and the drug should be discontinued if such symptoms occur. The symptoms of severe hyperglycemia include weakness, excessive eating, excessive thirst, and excessive urination.
- 52. Physicians should educate patients and their family members about the risk of serious hyperglycemia associated with quetiapine fumarate and how to identify the symptoms of hyperglycemia.
- 53. The Ministry of Health, Labor, and Welfare in Japan ordered this warning for AstraZeneca's quetiapine fumarate (Seroquel) after the Ministry received case reports of serious

side effects, including death, elevated levels of blood glucose, diabetic ketoacidosis, and coma since the drug's launch in that country.

- 54. While warning of the association of Seroquel with diabetes, glucose dysregulation, ketoacidosis, weight gain and the need for medical monitoring in Japan, Defendants failed to provide the same or similar warning to the public and prescribing physicians in the United States.
- 55. When placed in the stream of commerce, Seroquel was not accompanied by any meaningful warnings regarding the significant risk of diabetes mellitus and other problems associated with the ingestion of Seroquel. The warnings given by the Defendants did not accurately reflect the existence of the risk, let alone the incidence, symptoms, scope, or severity of such injuries.
- 56. Defendants failed to perform adequate testing concerning the safety of the drug Seroquel in that adequate testing would have shown that Seroquel poses a serious risk of diabetes mellitus and other problems which would have permitted adequate and appropriate warnings to have been given by Defendants to prescribing physicians and the consuming public.
- 57. Defendants failed to effectively warn users and physicians that numerous other anti-psychotic medications, including other atypicals, should be the first or exclusive method of treating schizophrenia and bipolar mania, particularly for certain high risk individuals.
- 58. Defendants had a duty to exercise reasonable care in the design, manufacture, sale, and distribution of the drug Seroquel, including a duty to assure that the product did not cause users to suffer from unreasonable, dangerous side effects when used alone or in foreseeable combination with other drugs.

- 59. Defendants were negligent in the design, manufacturing, testing, advertising, marketing, promotion, labeling, warnings given, and sale of Seroquel in that, among other things, they:
  - a. Failed to accompany the product with proper warnings regarding the serious adverse side effects, including diabetes mellitus, ketoacidosis, coma, death, hyperglycemia, weight gain, and glucose dysregulation associated with the use of Seroquel;
  - b. Failed to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the drug Seroquel;
  - c. Failed to provide adequate training and instruction to medical care providers for appropriate use of the drug Seroquel;
  - d. Failed to warn Plaintiff prior to actively encouraging the sale of Seroquel, either directly or indirectly (through the prescribing physician), orally or in writing, about the following:
    - the need for a battery of diagnostic tests to be performed on the patient prior to ingesting Seroquel to discover and ensure against potentially fatal side effects; or
    - the need for comprehensive, regular medical monitoring to ensure early discovery of potentially fatal side effects;
  - e. Failed to warn that the risks associated with the ingestion of Seroquel exceeded the risks of other comparable forms of medication for schizophrenia;

- f. Failed to effectively warn about the increased danger and potentially fatal relationship in combining use of Seroquel with various other drugs or use with certain identifiable disorders;
- g. Negligently marketed Seroquel, despite the fact that the risks of the drug were so high and the benefits of the drug were so speculative that no reasonable pharmaceutical company exercising due care would have done so;
- h. Recklessly, falsely, and deceptively represented or knowingly omitted, suppressed, or concealed material facts regarding the safety and efficacy of Seroquel from prescribing physicians and the consuming public, and that had prescribing physicians and the consuming public known of such facts, the drug Seroquel would never have been prescribed to, or used by, Plaintiff;
- i. Remained silent despite their knowledge of the growing acceptance by the public and physicians of misinformation and misrepresentations regarding both the safety and efficacy of the ingestion of Seroquel, and did so because the prospect of huge profits outweighed health and safety issues, all to the significant detriment of Plaintiff;
- j. Failed to perform their post-manufacturing and continuing duty to warn which arose when they knew, or with reasonable certainty should have known, that their drug was being prescribed in a fatal or injurious combination or manner; and

- Were otherwise careless, negligent, grossly negligent, reckless, and acted
   with willful and wanton disregard for the rights of Plaintiff.
- 60. Despite the fact that Defendants knew or should have known that Seroquel caused unreasonable, dangerous side effects which many users would be unable to remedy by any means, Defendants continued to market Seroquel to physicians and consumers, including Plaintiff, when there were safer alternative methods of treating schizophrenia and bipolar mania.
- 61. Defendants knew or should have known that consumers such as Plaintiff Robert Burgett, Jr. would foreseeably suffer injury as a result of the Defendants' failure to exercise ordinary care as described above.
- 62. As a direct and proximate result of said negligent acts by Defendants, Plaintiff has suffered injuries and damages as described herein.

### COUNT II – FRAUD

- 63. Plaintiff repeats and realleges the allegations set forth in the paragraphs above as if fully set forth herein.
- 64. Defendants knew or should have known that Seroquel was dangerous and not as effective for its purpose as represented, and posed greater risks than disclosed, and was otherwise not as represented, as previously alleged.
- Defendants were under a duty to disclose this information to the Plaintiff because Defendants made representations and partial disclosures concerning the nature and quality of their product which they had a duty to correct because Defendants were in a superior position to know the true state of the facts about the dangerous and defective nature of Seroquel and its known risks to the Plaintiff. These deliberate and/or intentional omissions of material facts and misrepresentations include but are not limited to:

- a. suppressing, failing to disclose and mischaracterizing the known risks of ingesting Seroquel;
- b. omitting material information showing that Seroquel was no more effective than other anti-psychotic drugs on the market available;
- c. failure to timely and fully disclose the actual results of clinical tests and studies related to Seroquel;
- d. failing to issue adequate warnings concerning the risks and dangers of ingesting Seroquel which would disclose the nature and extent of the side effects of Seroquel;
- e. failing to disclose that adequate and/or standard and/or generally accepted standards for pre-clinical and clinical testing had not been done;
- f. failing to disclose that adequate and/or standard and/or generally accepted standards for post-marketing testing had not been done;
- g. making the representations concerning the safety, efficacy and benefits of Seroquel as detailed in this Complaint without full and adequate disclosure of the underlying facts which rendered such statements false and misleading.
- 66. Plaintiff did not know, and could not learn, the material facts and important information Defendants omitted and suppressed. The facts and information suppressed and concealed by Defendants are material and of such a nature that it can be reasonably presumed that the suppression and concealment of such facts caused, contributed to, and/or was a substantial factor in the Plaintiff's decision to ingest Seroquel.

- 67. As a result of Defendants' fraud, suppression and omission of material facts, Plaintiff acted to Plaintiff's detriment in purchasing and ingesting Seroquel, which Plaintiff would not have purchased or ingested had Plaintiff been told the truth, and should be reimbursed what Plaintiff spent.
- 68. As a direct and proximate result of said acts by Defendants, Plaintiff has suffered injuries and damages as described herein.

### **COUNT III**

### STRICT PRODUCT LIABILITY

### (Failure to Warn)

- 69. Plaintiff repeats and realleges the allegations set forth in the paragraphs above as if fully set forth herein.
- 70. The Seroquel manufactured and/or supplied by Defendants was and is unaccompanied by proper warnings regarding all known adverse side effects and the comparative severity and duration of such adverse effects. The warnings given did not and do not accurately reflect the severity or duration of the adverse side effects or the true potential and/or likelihood or rate of the side effects. Defendants failed to perform adequate testing in that adequate testing would have shown that Seroquel possessed serious potential side effects with respect to which full and proper warnings accurately and fully reflecting symptoms, scope and severity should have been made with respect to the use of Seroquel. Had the testing been adequately performed, the product would have been allowed to enter the market, if at all, only with warnings that would have clearly and completely identified the risks and dangers of the drug.

- 71. The Seroquel manufactured and/or distributed and/or supplied by Defendants was defective due to inadequate post-marketing warning or instruction because Defendants failed to provide adequate warnings to physicians or consumers of Seroquel and continued to aggressively promote Seroquel.
- 72. As a result of the foregoing, Seroquel was a defective and unreasonably dangerous product.
- 73. As the proximate cause and legal result of the defective condition of Seroquel as manufactured and/or supplied and/or distributed by Defendants, and as a direct and legal result of the negligence, carelessness, other wrongdoing and action(s) of Defendants described herein, the Plaintiff has suffered injuries and damages as described herein.

### COUNT IV

# STRICT PRODUCT LIABILITY

# (Pursuant to Restatement Second of Torts 402a (1965))

- 74. Plaintiff repeats and realleges the allegations set forth in the paragraphs above as if fully set forth herein.
- 75. The Seroquel manufactured and/or distributed and/or supplied by Defendants was defective in design or formulation in that when it left the hands of the manufacturers and/or suppliers and/or distributors, the foreseeable risks exceeded the benefits associated with the design or formulation.
- 76. Alternatively, the Seroquel manufactured and/or distributed and/or supplied by Defendants was defective in design or formulation in that when it left the hands of the manufacturer and/or suppliers and/or distributors, it was unreasonably dangerous, it was more

dangerous than an ordinary consumer would expect, and more dangerous than other antipsychotic drugs.

- 77. There existed, at all times material hereto, safer alternative medications.
- 78. Defendants did not perform adequate testing on Seroquel. Adequate testing would have shown that Seroquel caused serious adverse effects with respect to which full and proper warnings accurately and fully reflecting symptoms, scope and severity should have been made.
- 79. As a direct and proximate result of the defective condition of Seroquel, Plaintiff has suffered injuries and damages as described herein.

### **COUNT V**

### **BREACH OF EXPRESS WARRANTY**

- 80. Plaintiff repeats and realleges the allegations set forth in the paragraphs above as if fully set forth herein.
- 81. Defendants expressly warranted that Seroquel was safe and effective based on clinical studies.
- 82. Seroquel does not conform to these express representations because Seroquel is not safe and has high levels of serious, life-threatening side effects.
- 83. As a direct and proximate result of said breach of warranty, Plaintiff has suffered injuries and damages as described herein.

### COUNT VI

### **BREACH OF IMPLIED WARRANTY**

84. Plaintiff repeats and realleges the allegations set forth in the paragraphs above as if fully set forth herein.

- 85. At the time Defendants marketed, sold and distributed Seroquel for use by Plaintiff and the consuming population, Defendants knew of the use for which Seroquel was intended and impliedly warranted Seroquel to be of merchantable quality and safe and fit for such use.
- 86. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether Seroquel was of merchantable quality and safe and fit for its intended use.
- 87. Contrary to such implied warranty, Seroquel was not of merchantable quality or safe or fit for its intended use because Seroquel was and is unreasonably dangerous and unfit for the ordinary purposes for which it was used as described above.
- 88. As a direct and proximate result of said breach of warranty, Plaintiff has suffered injuries and damages as described herein.

### COUNT VII

# CONCEALMENT, SUPPRESSION, OR OMISSION OF MATERIAL FACTS

- 89. Plaintiff repeats and realleges the allegations set forth in the paragraphs above as if fully set forth herein.
- 90. Defendants omitted, suppressed, or concealed material facts concerning the dangers and risks associated with the use of Seroquel, including but not limited to the risks of diabetes mellitus and other injuries. Further, Defendants purposely downplayed and understated the serious nature of the risks associated with Seroquel use in order to increase the sales of Seroquel.
- 91. Defendants falsely and deceptively misrepresented or knowingly omitted, suppressed, or concealed facts of such materiality that the drug would never have been approved and no reasonable physician would have prescribed this drug to Plaintiff.

- 92. Defendants knew or should have known (or would have known had appropriate testing been done) that use of Seroquel caused serious and potentially life-threatening side effects of diabetes, pancreatitis, and other hyperglycemia-related adverse events.
- 93. Defendants engaged in calculated silence, despite their knowledge of the growing public acceptance of misinformation and misrepresentations regarding both the safety and efficacy of the use of Seroquel, and did so because the prospect of significant future profits caused them to ignore concerns regarding health and safety issues, all to the significant detriment of the public, including the Plaintiff.
- 94. Safer and less expensive anti-psychotics were available to patients being treated with Seroquel.
- 95. Defendants purposefully downplayed the side effects or provided misinformation about adverse reactions and potential harms from Seroquel and succeeded in persuading large segments of the relevant consumer market to request, i.e., the average consumer, and large segments of the medical community to prescribe Seroquel, despite both the lack of efficacy and the presence of significant dangers as set forth herein.
- 96. Defendants had a post-manufacturing and continuing duty to warn, which arose when they knew, or with reasonable care should have known, that Seroquel was injurious or fatal.
- 97. Defendants omitted, suppressed, or concealed material facts concerning the dangers and risks associated with the use of Seroquel, including but not limited to the risks of death, disease and other health problems associated with the use of Seroquel. Defendants have purposely downplayed and/or understated the serious nature of the risks associated with the use

of Seroquel and have implicitly encouraged the use of this drug despite knowledge of the dangerous side effects that this drug presents to the patient population.

- 98. Defendants knew or should have known, and would have known had appropriate testing been done, that the use of Seroquel caused the serious and potentially life threatening side effects of adverse health-related problems or death.
- 99. Defendants' actions, as set forth herein, constitute knowing omission, suppression or concealment of material fact, made with the intent that others will rely upon such concealment, suppression or omission in connection with the marketing, sale and use of Seroquel.
- 100. In fact, the Plaintiff, directly and/or through Plaintiff's prescribing physician, was induced by the Defendants' omission, suppression and concealment to use Seroquel.
- 101. As a direct and proximate result of the conduct of Defendants as described herein, the Plaintiff has suffered injuries and damages as described herein.

### COUNT VIII – DAMAGES

- 102. Plaintiff repeats and realleges the allegations set forth in the paragraphs above as if fully set forth herein.
- 103. As a direct and proximate result of the aforesaid acts and failure to act by Defendants, Plaintiff Robert Burgett, Jr. has suffered and will continue to suffer from serious permanent physical injuries, including diabetes, pain and suffering and mental anguish, and will suffer loss of enjoyment of life, has and will continue in the future, for an indefinite time, to be obligated to receive and undergo medical attention and care and to incur medical expenses, has incurred and will in the future incur, other financial expenses, lost earnings and special damages, and has and will continue to worry, fear and have anguish over her diabetes mellitus and related

health problems and about future health problems arising from the aforementioned use of

Seroquel.

WHEREFORE, Plaintiff Robert Burgett, Jr. demands joint and several relief as follows:

(a) General and special compensatory damages for personal injury, permanent

physical injury, pain and suffering, mental anguish, loss of enjoyment of life, and

economic loss;

(b) Punitive damages against Defendants for their reckless, willful and wanton

conduct;

(c) Attorneys' fees and costs; and

(d) Such other remedies as this Honorable Court may deem just and appropriate.

Respectfully submitted,

/s/ William L. Bross W. Lewis Garrison, Jr. William L. Bross

OF COUNSEL:

HENINGER GARRISON DAVIS, LLC

2224 First Avenue North Birmingham, AL 35203

Telephone: (205) 326-3336

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PLAINTIFF DEMANDS TRIAL BY STRUCK JURY ON ALL ISSUES RAISED HEREIN

/s/ William L. Bross OF COUNSEL

# Serve Defendants by Certified Mail:

AstraZeneca LP c/o Corporation Company 2000 Interstate Park Drive, Suite 204 Montgomery, AL 36109

AstraZeneca Pharmaceuticals LP c/o Corporation Company 2000 Interstate Park Drive, Suite 204 Montgomery, AL 36109

Zeneca, Inc. c/o Corporation Company 2000 Interstate Park Drive, Suite 204 Montgomery, AL 36109